

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of) Examiner: Not Assigned
Burbank et al.) Group Art Unit: Not Assigned
For: **METHODS AND APPARATUS FOR**) Customer No.: 23422
SECURING MEDICAL INSTRUMENTS)
TO DESIRED LOCATIONS IN A)
PATIENT'S BODY)
Serial No.: Not Assigned)
Filed: December 4, 2001)
Docket. No.: 9619-1012)

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PRELIMINARY AMENDMENT AND
INFORMATION DISCLOSURE
STATEMENT

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BOX PATENT APPLICATION
Commissioner for Patents
U.S. Patent and Trademark Office
Washington, D.C. 20231

Dear Sir:

Please amend the specification and claims as follow.

IN THE SPECIFICATION

On page 1, after the title, please insert:

"This application is a continuation of copending U.S. Patent Application Serial No. 09/146,185, filed September 1, 1998, by Burbank et al., which is a continuation-in-part of copending U.S. Patent application Serial No. 09/057,303, filed April 13, 1998, by Burbank et al., which is a non-provisional application of U.S. Provisional Patent Application Serial No. 60/076,093, filed March 3, 1998, by Burbank et al., priority to which applications is claimed under 35 U.S.C. §§119(e) and 120 as applicable.

IN THE CLAIMS

Please cancel claims 2-48.

Please amend claim 1 as follows:

1. (Amended) A medical device for localization of target tissue comprising:

a shaft having a distal end, a proximal end defining a proximal direction, and a side, said distal end having a distal tip, said shaft being configured for placement of said distal end into a patient's body at a desired location;

a distal cutting element disposed on said distal tip; and

a fixation element disposed on said distal end, said fixation element being configured for securing the distal end of said medical device adjacent target tissue at said desired location.

Please add the following new claims:

49. The medical device of claim 1, wherein said distal cutting element is an electrosurgical cutting element.

50. The medical device of claim 49, wherein said distal cutting element is spaced away from said distal tip.

51. The medical device of claim 1, wherein said fixation element is disposed on said distal end proximal of said distal tip.

52. The medical device of claim 1, wherein said fixation element is configured for penetrating tissue.

53. The medical device of claim 51, wherein said fixation element comprises at least one radially extendable and retractable member which is radially extendable and retractable from a side of the distal end of the shaft, said member having a free end and being configured for securing the distal end of the shaft adjacent target tissue.

54. The medical device of claim 53, wherein said fixation element comprises a plurality of radially extendable and retractable members which are radially extendable and retractable from a side of the distal end of the shaft, said members having free ends and being configured for securing the distal end of the shaft adjacent target tissue.

55. A method of performing a medical procedure using a medical device comprising a shaft having a distal end, a proximal end, a fixation element, and a longitudinal axis defining a radial direction generally perpendicular to said axis, comprising:

- a) placing the distal end of the shaft in a patient's body, so that the distal end is disposed adjacent target tissue; and
- b) extending into the target tissue a fixation element from a side of the shaft spaced proximal to the distal end, said member having a free end configured for engaging tissue, so that the distal end of the shaft becomes secured adjacent the target tissue.

56. The method of claim 55, wherein said fixation element comprises at least one radially extendable and retractable member.

57. The method of claim 55, wherein said fixation element comprises a plurality of radially extendable and retractable members.

58. A method of performing a medical procedure using a medical device comprising a shaft having a distal end, a distal cutting element, a proximal end, a fixation element, and a longitudinal axis defining a radial direction generally perpendicular to said axis, comprising:

- a) cutting with said distal cutting element;
- b) placing the distal end of the shaft in a patient's body, so that the distal end is disposed adjacent target tissue; and
- c) extending into the target tissue a fixation element from a side of the shaft spaced proximal to the distal end, said member having a free end configured for engaging tissue, so that the distal end of the shaft becomes secured adjacent the target tissue.

59. The method of claim 58, wherein said fixation element comprises at least one radially extendable and retractable member.

60. The method of claim 58, wherein said fixation element comprises a plurality of radially extendable and retractable members.

61. The method of claim 58, wherein said distal cutting element is an electrosurgical cutting element.

62. The method of claim 58, wherein said cutting step comprises cutting target tissue.

63. The method of claim 58, wherein said cutting step comprises cutting through target tissue.

64. The method of claim 63, wherein said placing step comprises placing the distal end of the shaft in a patient's body so that the distal end is disposed adjacent and distal to target tissue.

65. A method for acquiring target tissue using a tissue acquisition device having a shaft with a distal end, a proximal end, a fixation element, and a longitudinal axis defining a radial direction generally perpendicular to the axis, comprising:

- a) placing the distal end of the shaft in a patient's body, so that the distal end is disposed adjacent the target tissue;
- b) securing the distal end of the shaft adjacent the target tissue by extending into the target tissue a fixation element from a side of the shaft spaced proximal to the distal end, said fixation element having a free end configured for engaging tissue; and
- c) acquiring one or more tissue samples of target tissue.

66. The method of claim 65, wherein the step of securing the distal end of the shaft comprises extending at least one radially extendable and retractable member from a side of the shaft spaced proximal to the distal end.

67. The method of claim 66, wherein the step of securing the distal end of the shaft comprises extending a plurality of radially extendable and retractable members from a side of the shaft spaced proximal to the distal end.

REMARKS

Entry of the above amendments is respectfully requested. With the amendments, the specification reflects the priority of the application and claims 1 and 49-67 are pending.

No new matter is added by way of the amendments or new claims, which find support throughout the specification and in the Figures as originally filed. In particular, support for the amended claim and for the new claims may be found, for example, in Figs. 13-15, and in the specification at, for example, page 15, lines 1-8, page 16, lines 24-27, and page 17, lines 1-14.

Applicants wish to bring to the attention of the Patent Office the references listed on the attached PTO-1449 form and request that they be considered by the Examiner. Each of the references cited on the attached was previously cited by or submitted to the PTO in prior application Serial No. 09/146,185, filed September 1, 1998, therefore no copies are enclosed.

Consideration and early notification of allowance of the pending claims is earnestly requested.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A medical device for localization of target tissue comprising:
a [tube] shaft having a distal end, a proximal end defining a proximal direction, and a side, said distal end having a distal tip, [longitudinal axis, the device]
said shaft being [adapted] configured for placement of said distal end into a patient's body at a desired location[,];
a distal cutting element disposed on said distal tip; and
[said medical device having] a fixation [agent] element disposed on said distal end, [the] said fixation [agent] element being [adapted] configured for [affixing]
securing the distal end of said medical device adjacent target tissue at said desired location.

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